

AMENDMENTS TO THE DRAWINGS:

The attached sheet of drawings includes a new Figure 4. The New Sheet, which includes new Figure 4 illustrates an example medical implant having a substantially constant thread height and a substantially constant pitch in accordance with an example embodiment of the present disclosure. Applicants respectfully content that Figure 4 does not add any new subject matter to the present application. See, for example, Applicants remarks under the “Objections to the Specification” heading below.

Attachment: New Sheet

REMARKS

This Application has been carefully reviewed in light of the *Office Action*. At the time of the Office Action, Claims 40-44, 46-57, 62, 63, and 67-70 were pending, of which the Examiner rejected Claims 40-44, 46-57, 62, 63, and 67-70. Applicants respectfully request reconsideration and favorable action in this case.

Objections to the Specification

The Examiner objects to the Specification under M.P.E.P. § 608.01 because the Specification allegedly does not provide sufficient antecedent basis for the terms “substantially constant pitch” and “substantially constant thread height.” Applicants respectfully traverse this objection. According to the M.P.E.P., “[i]n establishing a disclosure, applicant may rely not only on the specification and drawing as filed but also on the original claims if their content justifies it.” §608.04. Moreover, in establishing a disclosure, “the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.” See *id.* at §2163.02. Accordingly, Applicants respectfully direct the Examiner’s attention to Claim 14 as originally filed. More particularly, originally file Claim 14 is directed to a medical implant “wherein the thread height of each of the one or more threads is 0.032 inches.” Additionally, originally filed Claim 14 states, “the pitch of the one or more threads is 0.090 inches.” Accordingly, Applicants respectfully contend that the Application conveys a “substantially constant thread height” and a “substantially constant pitch” with reasonable clarity to those skilled in the art as of the filing date sought.

Section 112 Rejections of Claims 46, 48, 49, 65 and 70

The Examiner rejects Claims 46, 48, 49, 65 and 70 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Solely to advance prosecution in this matter, Applicants have amended each of Claims 46, 48, 49, 65 and 70 in a fashion whereby the Examiner’s rejections under 35 U.S.C. § 112 have been rendered moot.

Section 102 Rejections

The Examiner rejects Claims 40, 41, 50, 52, 53, 55, 56, 62, and 66 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,607,304 (“*Bailey*”). The

Examiner further rejects Claims 40, 41, 44, 47, 50, 52-56, 62, 63, 66 and 70 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,683,460 to Persoons (“*Persoons*”). Applicants respectfully traverse these rejections for the reasons stated below.

I. Legal Standard for 35 U.S.C. §102.

With regard to 35 U.S.C. § 102 “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *See* M.P.E.P. § 2131. In addition, “[t]he identical invention must be shown in complete detail as contained in the . . . claim [and] [t]he elements must be arranged as required by the claim.” *Id.* Likewise, if a drawing is relied upon as a source of potential prior art, “the picture must show all the claimed structural features and how they are put together.” *See* M.P.E.P. § 2125. Furthermore, “[i]n determining that quantum of prior art disclosure which is necessary to declare an applicant’s invention ‘not novel’ or ‘anticipated’ within section 102, the stated test is whether a reference contains an ‘enabling disclosure.’” *See* M.P.E.P. § 2121.01.

II. None of the cited references disclose a leading flank and a trailing flank as generally required by Claims 41, 56, and 70.

Claim 41 is directed to a medical implant that includes a body. The body has been configured to fit precisely into a sinus tarsi of a subtalar joint in a human foot. Furthermore, the body includes a first end having a first diameter and a second end having a second diameter. The body further includes at least one continuous and uninterrupted thread that includes a crest with a substantially flat surface and having a substantially constant thread height. The thread helically traverses an entire length of an exterior surface of the body wherein the length spans from the first end to the second end. Furthermore, the thread includes a leading flank inclined away from the second end and spanning from the crest to a thread root and a trailing flank inclined away from the first end and spanning from the crest to the thread root. Additionally, the leading flank is separated from the trailing flank by a thread angle. Furthermore, a circumference of the exterior surface tapers from the first diameter to the second diameter along the length of the body. The body further has a recessed engagement in the first end. Neither *Bailey* nor *Persoons* disclose each of these limitations.

For example, the thread of Claims 41 “includes a leading flank inclined away from the second end and spanning from the crest to a thread root and a trailing flank inclined away

from the first end and spanning from the crest to the thread root, the leading flank separated from the trailing flank by a thread angle.” Applicants respectfully contend that none of the cited references, including *Persoons* and *Bailey*, disclose these limitations. Accordingly, Applicants respectfully contend that Claims 41 each of its dependent claims are in condition for allowance. Similar to Claim 41, Claims 56, and 70 each include limitations generally directed to a thread that includes a leading flank inclined away from the second end and a trailing flank inclined away from the first end wherein the leading flank is separated from the trailing flank by a thread angle. For reasons similar to those explained with respect to Claim 41, Applicants respectfully contend that Claims 56 and 70 and each of their respective dependent claims are in condition for allowance.

III. Neither Bailey nor Persoons disclose “a body configured to fit precisely into a sinus tarsi of a subtalar joint” as generally required by Claims 40, 55, and 70.

Claim 40 is directed, in part, to a medical implant having “a body configured to fit precisely into a sinus tarsi of a subtalar joint in a human foot.” Neither *Bailey* nor *Persoons* disclose these limitations. As explained above, to sustain a rejection under §102, the Examiner must show that each and every element of a claim is **described** in a single reference. However, to account for the fact that neither *Bailey* nor *Persoons* disclose, “a body configured to fit precisely into a sinus tarsi,” the Examiner argues that the alleged medical implants of *Bailey* and *Persoons* are “capable of placement” in a sinus tarsi. Respectfully, this argument falls short of the §102 standard. *Bailey* and *Persoons* **do not** describe the limitations at issue and the Examiner cannot interpret them as doing so.

To further clarify, the Examiner’s statement that the alleged medical implants of *Bailey* and *Persoons* are “capable of placement” in a sinus tarsi does not establish a §102(b) description of the invention. The alleged medical implants of *Bailey* and *Persoons* are not described as being configured to perform the limitations of the claims at issue; therefore, neither *Bailey* nor *Persoons* qualify as a §102(b) reference no matter how the Examiner is interpreting them. The strictures of §102 must be followed as described above in order to define a legitimate body of prior art. Consequently, the Examiner cannot rely on his interpretation of a reference to establish anticipation under §102. Accordingly, Applicants respectfully contend that Claim 40 and each of its dependent claims are in condition for allowance. Additionally, Claims 55 and 70 include limitations generally directed to a body configured to fit precisely into a sinus tarsi of a subtalar joint in a human foot. For reasons

similar to those explained with respect to Claim 40, Applicants respectfully contend that Claims 55 and 70 and each of their respective dependent claims are in condition for allowance.

III. Persoons does not disclose an engagement comprising: a hexagonal portion, a cylindrical portion, and a countersink portion as required by Claim 44.

Applicants have amended Claim 44 into independent form to include each of the limitations of its base claims. Applicants respectfully contend that Applicants' amendment did not add any new subject matter to Claim 44. Applicants respectfully contend that the Examiner's rejection of Claim 44 in the *Office Action* was improper. Claim 44 is directed, in part, to an "engagement compris[ing]: a hexagonal portion, a cylindrical portion, and a countersink portion." The Examiner relies on *Persoons* to reject Claim 44 under 102(b); however, *Persoons* does not disclose these limitations as the Examiner later admits in the *Office Action*. See *Office Action*, page 7 ("[*Persoons*] does not show details of the recess and bore (the claimed hexagonal, cylindrical, and countersunk is not shown)"). Accordingly, since *Persoon's* does disclose "each and every element" of Claim 44, Applicants respectfully request that the Examiner withdraw the rejection of Claim 44 under §102.

Section 103 Rejections

The Examiner rejects Claims 43, 46, 48, 49, 51, and 65 under 35 U.S.C. § 103(a) as allegedly being unpatentable over *Bailey*. The Examiner rejects Claims 40, 46, 48-50, 52, 53, 55, 65, and 66 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,961,524 to Crombie ("*Crombie*"). The Examiner rejects Claims 42 and 57 under 35 U.S.C. § 103(a) as allegedly being unpatentable over *Persoons* in view of U.S. Patent No. 5,951,560 to Simon et al. ("*Simon*"). The Examiner rejects Claims 67-70 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Publication No. 2004/0097928 A1 by Zdeblick et al. ("*Zdeblick*") in view of U.S. Patent No. 5,897,593 to Kohrs et al. ("*Kohrs*"). Applicants respectfully traverse these rejections for the reasons stated below.

IV. None of the cited references teach, disclose, or suggest a leading flank and a trailing flank as generally required by Claims 41, 56, 67, and 70.

As explained above, Claims 41 is directed to the medical implant of claim 40 wherein, "the thread includes a leading flank inclined away from the second end and spanning from the crest to a thread root and a trailing flank inclined away from the first end and spanning

from the crest to the thread root.” Additionally, Claims 56, 67, and 70 include similar limitations. Applicants respectfully contend that none of the cited references disclose, teach, or suggest these limitations. Accordingly, Applicants respectfully contend that each of the claims depending from Claims 41 and 56 (i.e., claims 43, 46, 48, 49, 51, and 65 as rejected under *Bailey*, Claims 46, 48-50, 52, 53, 65, and 66 as rejected under *Crombie*, Claims 42 and 57 as rejected under *Persoons* in view of *Simon*, and Claims 67-70 as rejected under *Zdeblick* in view of *Kohrs*) are in condition for allowance.

V. Crombie does not teach, disclose, or suggest disclose “a body configured to fit precisely into a sinus tarsi” as generally required by Claims 40 and 55.

Claim 40 is directed, in part, to a medical implant having “a body configured to fit precisely into a sinus tarsi of a subtalar joint in a human foot.” *Crombie* does not disclose, teach, or suggest these limitations. However, to account for the fact that *Crombie* does not disclose, teach, or suggest “a body configured to fit precisely into a sinus tarsi,” the Examiner argues that the alleged medical implant of *Cormbie* is “capable of placement” in a sinus tarsi. Respectfully, this argument falls short of the §103 standard. The Examiner has not shown that these limitations are taught, disclosed, or suggested by *Crombie*, nor has the Examiner identified these limitations in another reference that may be properly combined with *Crombie* as required to sustain a rejection under §103. Merely stating that an alleged medical implant is “capable of placement” in a sinus tarsi does not disclose, teach, or suggest a medical implant having “a body configured to fit precisely into a sinus tarsi” as required by Claim 40. Accordingly, Applicants respectfully contend that Claim 40 and each of its dependent claims are in condition for allowance. Additionally, Claim 55 includes limitations generally directed to a body configured to fit precisely into a sinus tarsi of a subtalar joint in a human foot. For reasons similar to those explained with respect to Claim 40, Applicants respectfully contend that Claims 55 each of its respective dependent claims are in condition for allowance.

VI. Neither Zdeblick nor Kohrs disclose, teach, or suggest a leading flank and a trailing flank as generally required by Claims 67 and 70.

The Examiner further rejects Claims 67-70 under § 103(a) as allegedly being unpatentable over *Zdeblick* in view of *Kohrs*. Applicants respectfully traverse these rejections. Claims 67 is directed to a method of using a medical implant that “includes a leading flank inclined away from the second end and spanning from the crest to a thread root and a trailing flank inclined away from the first end and spanning from the crest to the thread

root, the leading flank separated from the trailing flank by a thread angle.” Applicants respectfully contend that none of the cited references, including *Zdeblick* and *Kohrs*, disclose these limitations. Accordingly, Applicants respectfully contend that Claim 67 and each of its dependent claims are in condition for allowance. Similar to Claim 67, Claims 70 includes limitations generally directed to a thread that includes a leading flank inclined away from the second end and a trailing flank inclined away from the first end wherein the leading flank is separated from the trailing flank by a thread angle. For reasons similar to those explained with respect to Claim 67, Applicants respectfully contend that Claims 70 is in condition for allowance.

VII. All claims are in condition for allowance

For at least the reasons explained above, Applicants respectfully contend that each and every one of the claims of the instance Application are in condition for allowance.

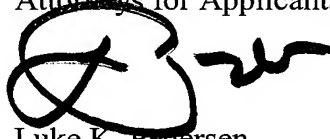
CONCLUSION

Applicants have made an earnest attempt to place this case in condition for allowance. For the foregoing reasons, and for other apparent reasons, Applicants respectfully request full allowance of all pending Claims. If the Examiner feels that a telephone conference or an interview would advance prosecution of this Application in any manner, the undersigned attorney for Applicants stands ready to conduct such a conference at the convenience of the Examiner.

The Examiner is authorized to charge the amount of **\$210.00** for the addition of one independent claim to Deposit Account No. 02-0384 of Baker Botts L.L.P. Please charge any additional fees or credit any overpayment to Deposit Account No. 02-0384 of Baker Botts L.L.P.

Respectfully submitted,

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ATTACHMENT